UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,959	02/26/2002	Seah H. Lim	010.00131	5006

7590 06/14/2007

Kathy Smith Dias Esq
Heslin Rothenberg Farley & Mesiti P C
5 Columbia Circle
Albany, NY 12203-5160

EXAMINER	
UNGAR, SUSAN NMN	
ART UNIT	PAPER NUMBER
1642	

MAIL DATE	DELIVERY MODE
06/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/082,959	LIM ET AL.	
	Examiner	Art Unit	
	Susan Ungar	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *April 16, 20007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) 6 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) 6 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. The Response filed April 16, 2007 in response to the Office Action of January 16, 2007 is acknowledged and has been entered. Claim 6 is currently being examined.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The following rejections are being maintained:

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 6 remains rejected under 35 USC 112, second paragraph for the reasons previously set forth in the Paper mailed January 16, 2007, Section 4, pages 2-4.

Applicant argues that Sp17 is not "the claimed protein" and that Sp17 is simply a protein that is recited by the claim at issue. Applicants have not now, nor ever sought to claim human Sp17 polypeptides, rather Applicant's claim is directed to isolated cytotoxic T cells. The argument has been considered but has not been found persuasive because although Applicant is correct in that the claim is drawn to an isolated cytotoxic T cell, given that T cells are defined by the antigen that they recognize, that is Sp17, given that the antigen is not defined, the cytotoxic T-cell is also not defined.

Applicant argues that the test for determining whether a claim is indefinite under 35 USC 112, second paragraph is whether a person of ordinary skill in the

art would be able to understand the language of the claim. Applicant argues that the level of skill in the art is high, that the human Sp17 polypeptide was well known and described in the prior art at the time of filing and the detailed description consistently refers to the Sp17 protein and points to a number of scientific articles and patents regarding SP17 including Lea et al which lists the complete protein sequence.

The argument has been considered but has not been found persuasive because the claim is not limited to the Sp17 of Lea et al. Further, in the Response filed October 25, 2006, Applicant specifically argued, as set forth previously, that "to limit the antigen to a specific amino acid sequence, for example, the sequence of Lea et al, would not preclude the use of potential infringers of later identified polymorphisms of Sp17 that occur in the population and Applicant's patent protection would thereby be rendered meaningless." Thus, it is clear from Applicant's arguments that the recitation of the term human Sp17 is meant to include undefined and unlimited human Sp17 molecules and that the metes and bounds of the claimed patent protection cannot be determined.

Applicant reiterates arguments drawn to the NCBI database accession number of the Lea et al Sp17. The argument has previously been considered but has not been found persuasive for the reasons of record.

Applicant states that the assertion that they have refused to unambiguously identify the antigen recognized by the claimed isolated cytotoxic T cell in an attempt to broaden the scope of the originally claimed invention is a mischaracterization of the record. It is noted for the record, however that Applicant is mischaracterizing Examiner's assertion. Examiner never stated that Applicant refused to do anything, in particular Examiner asserted that "It appears

that Applicant's apparent refusal to unambiguously identify" which is a statement very different than that reported by Applicant.

Applicant reiterates arguments drawn to not claiming any SP17 polypeptides and that the recitation of 'Sp17" is merely an element of the claim. The argument has been considered above and is not convincing for the reasons set forth above.

Applicant argues that Applicant is not required to place identifiers in a claim where the recited protein is already known to those of skill in the art. The argument has been considered but has not been found persuasive because it is clear from Applicant's statements that they are not claiming that which is known to those of ordinary skill in the art, but rather that Applicant reads the claim as encompassing cytotoxic T cells that recognize "later identified polymorphisms of Sp17 that occur in the population" as well as undiscovered and unknown splice variants of Sp17.

6. Claim 6 remains rejected under 35 USC 112, first paragraph for the reasons previously set forth in the paper mailed January 16, 2007, Section 5, pages 4-9.

Applicant argues that Examiner's reliance on Eli Lilly and Enzo are misplaced because the instant case is distinguishable from Eli Lilly because the claimed invention does not concern the discovery of gene function or structure, rather the claimed invention of the instant application is focused on target recognition and that the instant application recites a cytotoxic T cell that recognizes human sperm protein 17, the complete structure of which was known and published prior to the filing date of the instant application.

The argument has been considered but has not been found persuasive because the case law cited by Examiner has established the principles required for

satisfaction of the written description requirement of 35 USC 112 and for the reasons of record, the specification does not meet those requirements.

Further, recognition of the target does in fact concern the discovery of a structure that is recognizable by the claimed cytotoxic T-cell. Further, like the Lilly case, Applicant is making a generic statement that is drawn to cytotoxic T cell that recognizes a generic Sp17 without more and this is not an adequate written description of the genus, it does not specifically define any of the gene products that fall within the claimed genus.

Applicant further argues that although Buchli et al, 2000 reports on a second gene and indicates that there is a possibility of additional Sp17 species within the human genome, the corresponding protein sequence is identical to that previously disclosed by Leah et al. The argument has been considered but its relevance is not clear. Examiner cited Buchli et al only to specifically make clear that Applicant's description of Sp17 in the paper submitted on October 25, 2006 was incorrect. Further, Applicant has not submitted a Leah et al reference. If Applicant is intending to refer to the Lea et al reference, previously submitted, it is noted that the claims are not limited to the Lea et al Sp17.

Applicant argues that the instant application can be distinguished from Enzo, wherein Enzo reaffirmed that deposit of a physical sample may replace words when description is beyond present capability. In the instant case, description is not beyond present scientific capability. The argument has been considered but has not been found persuasive because for the reasons of record, given Applicant's statements on the record, the description is beyond present scientific capability given that polymorphisms and other forms of Sp17 have not been defined and no correlation between structure and function has been defined. As previously set

forth, in the absence of that definition, the claimed cytotoxic T cell is not described.

Applicant cites Capon v. Eshbar to support the contention that "the determination of what is needed to support generic claims to biological subject matter depends on a variety of factors and it is not necessary for every permutation within a generally operable invention be effective in order for an inventor to obtain a generic claim, provided that the effect is sufficiently demonstrated to characterize a generic invention. The argument has been considered but has not been found persuasive because as previously set forth, only a single species is disclosed and for the reasons of record, this is not sufficient to sufficiently demonstrate and characterize the generic invention.

Applicant argues that in LizardTech, Inc. v. Earth Resource Mapping, PTY, the court ruled that it is unnecessary to spell out every detail of the invention in the specification, only enough must be included to convince a person of skill in the art that the inventor possessed the invention. Applicant argues that given the teaching in this case, given what was known in the art at the time the application was filed, the teaching of the specification provides an adequate written description of the claimed invention. The argument has been considered but has not been found persuasive because the LizardTech is not drawn to the biotechnology arts and is not analogous to the biotechnology art of cytotoxic T cells. Given that Applicant has not explained why the LizardTech findings are applicable to the instant invention, the findings of the court have not been evaluated.

Applicant argues that as described throughout the specification and Example sections, the Sp17-specific cytotoxic T cell of the claimed invention is donor-derived. The argument has been considered but has not been found persuasive

because Applicant is arguing limitations not recited in the claims as currently constituted.

Applicant discloses methods of using cytotoxic T-cells specific for Sp17. The disclosure has been considered but has not been found persuasive because the claims are not drawn to methods of using the exemplified donor-derived cytotoxic T-cells.

Applicant argues that Applicants' specific teachings can be used generally to achieve an isolated cytotoxic T cell to any human Sp17 protein because the protein is donor-derived and although polymorphisms are expected to exist in the human population, this does not change the value of Sp17 as a target in generating and isolating cytotoxic T cell that recognizes such a target. The argument has been considered but has not been found persuasive because Applicant is once again arguing limitations not recited in the claims as currently constituted.

6. No claims allowed

7. This action is a **final rejection** and is intended to close the prosecution of this application. Applicant's reply under 37 CFR 1.113 to this action is limited either to an appeal to the Board of Patent Appeals and Interferences or to an amendment complying with the requirements set forth below.

If applicant should desire to appeal any rejection made by the examiner, a Notice of Appeal must be filed within the period for reply identifying the rejected claim or claims appealed. The Notice of Appeal must be accompanied by the required appeal fee.

If applicant should desire to file an amendment, entry of a proposed amendment after final rejection cannot be made as a matter of right unless it merely cancels claims or complies with a formal requirement made earlier.

Amendments touching the merits of the application which otherwise might not be proper may be admitted upon a showing a good and sufficient reasons why they are necessary and why they were not presented earlier.

A reply under 37 CFR 1.113 to a final rejection must include the appeal from, or cancellation of, each rejected claim. The filing of an amendment after final rejection, whether or not it is entered, does not stop the running of the statutory period for reply to the final rejection unless the examiner holds the claims to be in condition for allowance. Accordingly, if a Notice of Appeal has not been filed properly within the period for reply, or any extension of this period obtained under either 37 CFR 1.136(a) or (b), the application will become abandoned. This action is a **final rejection** and is intended to close the prosecution of this application. Applicant's reply under 37 CFR 1.113 to this action is limited either to an appeal to the Board of Patent Appeals and Interferences or to an amendment complying with the requirements set forth below.

If applicant should desire to appeal any rejection made by the examiner, a Notice of Appeal must be filed within the period for reply identifying the rejected claim or claims appealed. The Notice of Appeal must be accompanied by the required appeal fee.

If applicant should desire to file an amendment, entry of a proposed amendment after final rejection cannot be made as a matter of right unless it merely cancels claims or complies with a formal requirement made earlier. Amendments touching the merits of the application which otherwise might not be proper may be admitted upon a showing a good and sufficient reasons why they are necessary and why they were not presented earlier.

A reply under 37 CFR 1.113 to a final rejection must include the appeal from, or cancellation of, each rejected claim. The filing of an amendment after final rejection, whether or not it is entered, does not stop the running of the statutory period for reply to the final rejection unless the examiner holds the claims to be in condition for allowance. Accordingly, if a Notice of Appeal has not been filed properly within the period for reply, or any extension of this period obtained under either 37 CFR 1.136(a) or (b), the application will become abandoned.

8 **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

9 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley, can be reached at 571-272-0898. The fax phone number for this Art Unit is (571) 273-8300.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar
Primary Patent Examiner
June 4, 2007